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09/831,546	08/24/2001	Jeffrey Errington	P02186USO	5951

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/831,546

Applicant(s)

ERRINGTON, JEFFREY

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-50 is/are allowed.
- 6) ☒ Claim(s) 20-41, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Non-Final Office Action is a Response to the "Amendment" filed 12 November 2002 (Paper No. 8) in reply to the Non-Final Office Action mailed 9 July 2002 (Paper No. 6). Claims 1-19 were considered in Paper No. 6. Claims 1-19 were canceled and claims 20-52 were added in Paper No. 8. Claims 20-52 are presently pending and under consideration.

#### ***Oath/Declaration***

A corrected Declaration has been received and entered in the case.

#### ***Response to Amendment***

Rejections set forth against claims 1-19 in Paper No. 6 are rendered moot by cancellation of the claims in Paper No. 8.

#### ***New Grounds***

#### ***Claim Objections***

Claim 32 is objected to because of the following informalities: The gene *ftsA* appears twice in the Markush group. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 31 and 33-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

In rejecting claims under 35 U.S.C. § 112, first paragraph, as lacking adequate written description in Paper No. 9, the examiner concludes, “only the described embodiments and those embodiments in which the functional status of the homologous gene or genes can be assessed using the reporter constructs of the described embodiments meet the written description provision of 35 U.S.C. § 112, first paragraph” (paragraph bridging pages 4 and 5). However, upon further consideration, it is apparent that the disclosure does not demonstrate possession commensurate with the full scope of claims directed to a *Bacillus* strain comprising a homologous cell division gene from another bacterium or methods of using said *Bacillus* strain. In the paragraph bridging pages 2 and 3, the specification states, “cell division genes include *divIB...divIC*, *divIVA*, *ftsA*, *ftsL...*, *ftsZ*, *pbpB*, as well as *spoOJ* and *spoIIIE*, and others, both known and to be discovered”. Beyond this, the specification does not set forth specific metes and bounds of a cell division gene, thus the term is understood according to its broadest reasonable

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interpretation to encompass any gene that when mutated disrupts the process of cell division. The claims therefore encompass a genus of *Bacillus* strains comprising a homologous gene involved in cell division, wherein said homologous gene can be one of the genes set forth or all genes involved in cell division, in some unspecified way, both known and unknown.

The Guidelines for Written Description state “The claimed invention as a whole may not be adequately described if the claims require an essential or critical element which is not adequately described in the specification and which is not conventional in the art” (see Federal Register, Vol. 66, No. 4, Column 3, page 71434). In the instant case, the homologous cell division gene is a critical element of the *Bacillus* strain. Therefore, adequate written description of said *Bacillus* strain requires adequate written description of the genus of cell division genes encompassed by the claims. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species, by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics (see MPEP 2163 (ii)). The disclosure provides nine examples of cell division genes (*Id.*) and reduces one of these examples to practice. However, the examples provided are structurally and functionally divergent and do not provide the skilled artisan with the means to recognize all genes belonging to the genus of cell division genes (i.e. relevant identifying characteristics).

Applicant merely states that the genes encompassed by the claim will have the function of a cell division gene and provides no structural basis for that function by which the skilled artisan could recognize other cell division genes. An adequate written description of a gene requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the gene itself. It is not sufficient to

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define gene solely by its principal biological property, i.e. it is somehow involved in cell division, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any gene with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all genes that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). With respect to the method claims, adequate description of the methods first requires an adequate description of the materials that provide the means for practicing the invention.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of all cell division genes. Therefore, only the genes specifically identified in the specification meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 28-30, 40, 41, 51 and 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for determining whether an agent inhibits the *outgrowth* (page 8, paragraph 2 of the specification) or inhibiting the *outgrowth* of a bacterium, does not reasonably provide enablement for a method for determining whether an

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agent inhibits the *growth* of a bacterium or a method of inhibiting the *growth* of a bacterium.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims of the instant invention are directed to a method for determining whether an agent inhibits the growth of a bacterium and methods of inhibiting the growth of bacteria. As the term “grow” is understood to mean expand in size as well as expand in population, the claims encompass methods of determining whether an agent inhibits the expansion in size of a bacterium or methods of inhibiting the expansion in size of a bacterium. Both the instant specification and prior art are silent regarding using the instant methods as a measure of bacterial size. Therefore, the skilled artisan would have to resort to trial and error experimentation, without any guidance from the instant application or prior art, to develop a means to measure bacterial size according to the claimed methods. As the teachings of the specification and prior art provide no expectation of success in measuring changes in the rate at which bacteria grow in size, the degree of experimentation required would clearly be undue. Substituting “outgrowth” for “growth” in the claims would obviate this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-41 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 20, and claims 21-30 as they depend therefrom, is indefinite in the recitation of “the DNA” in line 6. There is no antecedent basis for “the DNA” in the claim.

Claim 28 is also indefinite because the preamble of the claim does not match the outcome set forth in the terminal step. The claim is directed to a method of determining whether an agent inhibits SpoIIIE function, but the outcome set forth in the final step is provided as a measure of growth.

Claim 31, and claims 32-41 as they depend therefrom, are indefinite in the recitation of “(inactive)” in step (b). In the described method, the second reporter gene would provide a measure of the total synthesis of  $\sigma^F$  or  $\sigma^E$  factor, not only the  $\sigma^F$  or  $\sigma^E$  factor in the inactive state. It is therefore unclear how the second reporter gene is limited to a measure of inactive  $\sigma^F$  or  $\sigma^E$  factor.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 41 is rejected under 35 U.S.C. 102(b) as being anticipated by Liao *et al.* (1997) *J. Bacteriol.* 179:1490-1496.

Claim 41 is directed to a method of killing or inhibiting the growth of bacteria, comprising contacting the bacteria with an agent identified by the method of claim 40. The agent of claim 41 is a product by process limitation and thus reads on any agent that would give a positive result in the method of claim 40. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) states: “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a



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product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”

In the paragraph bridging columns 1 and 2 on page 1492, Liao *et al.* teaches a method of killing or inhibiting the growth of bacteria using  $\beta$ -lactam antibiotics. As the method of claim 40 is designed to measure inhibition of a protein such as pbpB, a target of  $\beta$ -lactam antibiotics, the agent of Liao *et al.* is the same as the agent of claim 40. Therefore the teachings of Liao *et al.* anticipate the claim.

#### ***Allowable Subject Matter***

Claims 42-50 are allowed.

Claims 20-27 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms

January 17, 2003



**JAMES KETTER  
PRIMARY EXAMINER**